

Application No. 10/651,671  
Amendment "A" and Response dated March 13, 2006  
Reply to Office Action of December 23, 2005

### REMARKS

Applicants and Applicants' attorney express appreciation to the Examiner and the Examiner's supervisor for the courtesies extended during the recent interview held on March 8, 2006. Reconsideration and allowance of the above-identified application are respectfully requested in view of the foregoing amendments and the following remarks. Claims 1-17 and 25-31 are pending, wherein claims 1, 11 and 16 have been amended, claims 18-24 were cancelled, and new claims 25-31 were added.

As discussed during the Examiner Interview, the disclosed tensioning systems permits the independent application of a tensile load onto different strands of a composite soft tissue graft attached to a bone tunnel. Because the different tissue graft strands may have differing diameters or stiffness, they will not provide their maximum utility as a composite tissue graft unless each graft strand is tensioned the correct amount. As discussed in the Application, failure to properly apply tension to each tissue graft strand results in a composite graft in which one of the strands is likely to bear most or all of the load. Application, ¶ [0016]. The strand that bears most or all of the load is more likely to break first, upon which the remaining strand will bear all of the load. The joint will also likely become excessively loose if one of the tissue graft strands breaks. None of the cited art discloses or suggests an apparatus capable of independently applying a separate load to each of a plurality of tissue graft strands. Nor do they even recognize the need of doing so.

Goble et al. (US 5,713,897) discloses a device that is only designed to apply a single tensile load to a tissue graft placed within a bone tunnel. Goble et al. neither teaches nor suggests a device having first and second adjustable tensioning apparatus capable of independently applying an appropriate tensile load to each of two soft tissue graft strands. In order to further distinguish over Goble et al., claims 1 and 11 were amended to specify that the tensioning portion of the tensioning device further includes a tensioning block to which the first and second adjustable tensioning apparatus are attached. The tensioning block maintains the first and second adjustable tensioning apparatus in a spaced-apart relationship with sufficient space therebetween that an interference screw can pass between the first and second adjustable tensioning apparatus while securing a soft tissue graft to the bone tunnel. Support for a tensioning block to which adjustable tensioning apparatus are attached in a spaced-apart relationship is found in the Application at paragraph [0064] and Figure 1. Space sufficient to

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insert an interference screw between the first and second adjustable tensioning apparatus is shown in Figure 19.

Because Goble et al. does not comprehend the need to include two different adjustable tensioning apparatus, Goble et al. certainly fails to teach or suggest a tensioning block that is able to maintain a predetermined amount of space between two different adjustable tensioning apparatus, let alone so as to permit an interference screw to pass therebetween. Because none of the other cited references disclose a tensioning apparatus, even if combined with Goble, the combined references would not teach or suggest every element in amended claims 1 and 11 by virtue of the tensioning block limitation alone. Moreover, Applicants believe the claims include other limitations that, in combination, are not suggested by the combination of references.

For example, Applicants do not believe that one of skill in the art would have been motivated to substitute pins 18 used to attach the tensioning device shown in Goble et al. with the breakaway pins disclosed in Neufeld (US 3,842,824). The pins in Neufeld are designed to break off below skin level. *See* Figure 1. Pins designed to break off below skin level would not provide any structure for attachment of the tensioning device of Goble et al. Thus, one of skill in the art would not have substituted the solid pins 18 of Goble et al. with the breakaway pins of Neufeld. For this additional reason Applicants believe claim 1 as amended is patentable over the combination of Goble et al. and Neufeld.

Applicants also do not believe that one of skill in the art would have been motivated to use the suture organizer of Jain (US 5,207,703) with the tensioning device of Goble et al. As taught in Goble et al., the sutures attached to the soft tissue graft in the bone tunnel are gathered together as a single bundle and attached to vertical post 53. *See* Figure 3; col. 7, ll. 27-31. There would be no reason to separate the sutures when using the device in Goble et al. To do so would serve no purpose and would likely inhibit the ability to properly attach the sutures to vertical post 53 as shown in Figures 3 and 4 of Goble et al. Accordingly, one of skill in the art would not have been motivated to utilize the suture organizer of Jain in combination with the tensioning device of Goble et al.

Moreover, the suture organizer of Jain would not work with the Goble et al. device even if the two reference were combined. The suture organizer is designed to lie flat on a surface of a bed containing a patient with sutures coming out of the patient's body, as shown in Figures 1 and 2 of Jain. Vertical pegs are provided to organize the sutures. Because the sutures coming out of

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the patient's body are not tensioned, the Jain device works well in organizing sutures in that situation. However, rather than remaining flaccid, the sutures used in Goble et al. are placed under high tension. The Jain device is not designed for use with highly tensioned sutures as used in Goble et al., particularly since the sutures are gathered together in a single highly tensioned bunch. Sutures gathered together in a single bunch as shown in Figures 3 and 4 of Goble cannot be organized using the Jain device, particularly when under tension. Accordingly, Applicants submit that claim 15 is further patentable over Goble et al. and Jain for this additional reason.

The Office Action indicates that claims 10 and 17 define patentable subject matter (*i.e.*, none of the cited references teach or suggest a tension calculator as recited therein). On this basis Applicants present new claim 25, which recites a tensioning system comprising a tensioning device capable of independently applying a tensile load to individual strands of a soft tissue graft and a tension calculator adapted for determining what portion of a total tensile load to be applied to a composite tissue graft is to be applied to each tissue graft strand individually. This allows the user to apply the correct tensile load to each tissue graft strand using the claimed tensioning device. Applicants believe that new claim 25 is patentable over the art of record, which neither teaches nor suggest the combination of features recited in new claim 25.

New claim 30 alternatively claims an embodiment suggested during the Examiner Interview, namely a tensioning system that includes breakaway guide pins that include a protrusion 246 as shown in Figure 12 to limit the depth to which the pins can be inserted into a bone. The breakaway pins of Neufeld do not include any such protrusion. Moreover, it would be contrary to Neufeld to include such a protrusion since that would limit penetration of the pins. In fact, the pins of Neufeld are intended to hold a broken hip bone together and must be free to penetrate deeply into the hip bone and then be capable of being broken off at a location below the skin. See Figure 1. For this reason, Applicants submit that new claim 30 is patentable over the art of record, which does not teach or suggest the combination of features recited in new claim 30.

New claims 26-29 and 31 contain subject matter found in the other claims and further distinguish over the cited art.

Finally, the Office Action rejects various claims under obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,679,889 to West, Jr. et al. Without acquiescing in this rejection, but in an effort to advance prosecution, Applicants are filing a

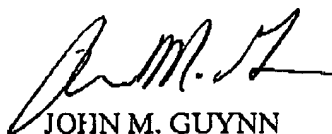
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Terminal Disclaimer herewith in order to remove any potential double patenting rejections relative to West, Jr. et al.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 13<sup>th</sup> day of March 2006.

Respectfully submitted,



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